

**Notice of Allowability**

Application No.

10/734,096

Examiner

Lora E. Barnhart

Applicant(s)

GOLDSTEIN ET AL.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE received 3/7/06.
2. ☒ The allowed claim(s) is/are 111-113, 115-119, 121-126, 135-141, 143-146, 151, 156 and 162.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____   |

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Magdalena O. Cilella on 5/3/06.

The application has been amended as follows:

Replace claim 111 in its entirety with the following:

- - - 111. A method of preparing a preserved tissue, comprising

providing an uncrosslinked tissue selected from the group consisting of heart valve leaflets, aortic roots, aortic walls, pulmonary valves, pulmonary conduits, non-valved conduits, mitral valves, monocusps, tendons, ligaments, fascia, blood vessels, arteries, veins, ureters, diaphragm, pericardium, umbilical cords, dura mater, and tympanic membranes;

providing an aqueous solution comprising between 15mM and 100mM bio-compatible buffer; between 5% and 30% polyvinylpyrrolidone (v/v); between 5% and 30% isopropanol (v/v); and between 0.1M and 1.5M ascorbate;

combining the aqueous solution with the uncrosslinked tissue;

lowering the temperature of the resulting composition to at least the freezing point of the aqueous solution; and

irradiating the tissue with ionizing radiation to produce a preserved tissue,

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wherein the denaturation temperature of the preserved tissue, when thawed, is reduced or increased by no more than 3°C as compared to the uncrosslinked tissue prior to combination with the aqueous solution.

In claim 112, line 1, replace "the tissue and solution" with - - - the uncrosslinked tissue and the aqueous solution - - -.

In claim 113, line 1, replace "said solution" with - - - said aqueous solution - - -.

Claim 114 is canceled.

Replace claim 115 in its entirety with the following:

- - - 115. The method of claim 111, further comprising subjecting said preserved tissue to extended storage and subsequently thawing said preserved tissue. - - -

In claim 116, line 1, replace "claim 114" with - - -claim 111- - -.

In claim 117, line 1, replace "claim 114" with - - -claim 111- - -.

In claim 118, line 2, replace "said tissue" with - - - said uncrosslinked tissue - - -.

Claim 120 is canceled.

In claim 121, line 1, replace "said tissue" with - - - said uncrosslinked tissue - - -.

In claim 122, lines 1-2, replace "said tissue" with - - - said uncrosslinked tissue - - -.

In claim 123, line 2, replace "said solution" with - - - said aqueous solution - - -.

In claim 123, line 2, replace "said tissue" with - - - said uncrosslinked tissue - - -.

In claim 124, line 1, replace "said solution" with - - - said aqueous solution - - -.

In claim 124, line 2, replace "said tissue" with - - - said uncrosslinked tissue - - -.

In claim 125, line 1, replace "said solution" with - - - said aqueous solution - - -.

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In claim 125, line 2, replace "said tissue" with - - - said uncrosslinked tissue - - -.

In claim 125, lines 2-3, replace "the solution" with - - - the aqueous solution - - -.

In claim 126, line 1, replace "said solution" with - - - said aqueous solution - - -.

In claim 126, line 2, replace "said tissue" with - - - said uncrosslinked tissue - - -.

Claims 127-134 are canceled.

In claim 135, line 2, replace "said solution" with - - - said aqueous solution - - -.

In claim 140, line 2, replace "said solution" with - - - said aqueous solution - - -.

In claim 141, line 2, replace "said solution" with - - - said aqueous solution - - -.

Claim 142 is canceled.

In claim 143, line 2, replace "said solution" with - - - said aqueous solution - - -.

In claim 145, line 2, replace "said solution" with - - - said aqueous solution - - -.

In claim 146, line 2, replace "said solution" with - - - said aqueous solution - - -.

Claims 147-150 are canceled.

Replace claim 151 in its entirety with the following:

- - - 151. The method of claim 111, wherein the aqueous solution comprises between 10% and 14% polyvinylpyrrolidone (v/v) - - -.

Claims 152-155 are canceled.

Replace claim 156 in its entirety with the following:

- - - 156. The method of claim 111, wherein the aqueous solution comprises about 15% isopropanol (v/v) - - -.

Claims 157-161 are canceled.

Replace claim 162 in its entirety with the following:

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- - - 162. The method of claim 111, wherein the aqueous solution comprises about 0.5M ascorbate - - - .

Claim 163 is canceled.

Claims 111-113, 115-119, 121-126, 135-141, 143-146, 151, 156, and 162 are allowed, as amended above where appropriate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

leb

SANDRA E. SAUCER  
PRIMARY EXAMINER

